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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/762,008

01/21/2004

Dieter Grob

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02/12/2007

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EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,008	GROB ET AL.	
	Examiner	Art Unit	
	Mary Hoffman	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8-24 and 38-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8-24 and 38-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/21/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/26/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8-12, 14-15, 18-19, 38, 43-49 and 52-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Fitz (U.S. Patent No 5,571,191).

Fitz discloses a cervical facet resurfacing implant comprising a superior implant (ref. #40) having an articulating surface and a fixation surface and configured for secured placement on a resurfaced superior articular facet of a selected cervical vertebra (col. 2, lines 20-25); and an inferior implant (ref. #50) having an articulating surface and a fixation surface and configured for secured placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical vertebra such that the articulating surface of the inferior implant interacts with the articular surface of the superior implant wherein at least one of the superior implant or the inferior implant comprises a tab (see FIG. 3) extending from a lateral edge of the implant, and wherein the tab has an aperture (ref. #54 or 56) for receiving a fixation device. The inferior implant further comprises a tab configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra. The tab is configured for attachment to the inferior articular

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process of the cervical vertebra or occiput immediately above the selected cervical vertebra with a screw. The tab extends from the remainder of the inferior implant to form an angle of from about 10 degrees to about 70 degrees. The inferior implant comprises a surface fixation mechanism (ref. #54 or 56). The surface fixation mechanism comprises at least one screw hole. The fixation surface of at least one of the inferior implant or the superior implant has at least one of: a porous coating, a porous onlay material, a biologic coating, a surface treatment, or a material facilitating ingrowth of bone (col. 3, lines 35-40). The inferior implant or the superior implant is composed of Ti/AlN (col. 2, line 3). The trans-lateral mass fixation mechanism is screw (ref. #58 or 60).

Claims 1-2, 4-6, 8-15, 20-24, 38-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Dooris et al. (U.S. Patent Applicant 2004/0127989).

Dooris et al. disclose a cervical facet resurfacing implant comprising a superior implant having an articulating surface and a fixation surface and configured for secured placement on a resurfaced superior articular facet of a selected cervical vertebra; and an inferior implant having an articulating surface and a fixation surface and configured for secured placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical vertebra such that the articulating surface of the inferior implant interacts with the articular surface of the superior implant wherein at least one of the superior implant or the inferior implant comprises a tab extending from a lateral edge of the implant, and wherein the tab has an aperture for receiving a fixation device (see FIG. 11). The superior implant and inferior implant are

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each generally disk-shaped. The superior implant comprises a tab configured for attachment to the lateral mass of the selected cervical vertebra. The tab is configured for attachment to the lateral mass of the selected cervical vertebra with a screw. The tab extends from the remainder of the superior implant to form an angle of from about 110 degrees to about 160 degrees. The inferior implant further comprises a tab configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra. The tab is configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra with a screw. The tab extends from the remainder of the inferior implant to form an angle of from about 10 degrees to about 70 degrees. At least one of the superior implant or the inferior implant comprises a surface fixation mechanism. The surface fixation mechanism comprises at least one of at least one peg, at least one pip, at least one fin, ridges, or at least one screw hole (paragraph [0118]). The surface fixation mechanism comprises multiple regions and wherein each of the regions has multiple ridges oriented in a different direction than the other regions (paragraph [0118]). The fixation surface of at least one of the inferior implant or the superior implant has a material facilitating ingrowth of bone (paragraph [0059]). The articulating surface of at least one of the inferior implant or the superior implant is composed of at least one of UHMWPE, i.e. a biocompatible material adapted for constraining but not eliminating relative movement (paragraph [0048]).

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Claims 1-2, 8-13 and 15-22, 24-47 and 49-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Soboleski et al. (U.S. Patent Application Publication 2002/0151895).

Soboleski et al. disclose a cervical facet resurfacing implant comprising a superior implant (ref. #16) having an articulating surface and a fixation surface and configured for secured placement on a resurfaced superior articular facet of a selected cervical vertebra (paragraph [0045-46]; and an inferior implant (ref. #12) having an articulating surface and a fixation surface and configured for secured placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical vertebra such that the articulating surface of the inferior implant interacts with the articular surface of the superior implant wherein at least one of the superior implant or the inferior implant comprises a tab extending from a lateral edge of the implant, and wherein the tab has an aperture for receiving a fixation device. The superior implant and inferior implant are each generally disk-shaped. The inferior implant further comprises a tab (e.g. see FIG. 3B, ref. #52) configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra. The tab is configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra with a screw. The tab extends from the remainder of the inferior implant to form an angle of from about 10 degrees to about 70 degrees. At least one of the superior implant or the inferior implant comprises a surface fixation mechanism. The surface fixation mechanism comprises at least one of at least one peg, at least one pip, at least

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one fin, ridges, or at least one screw hole (paragraph [0043]). The surface fixation mechanism comprises multiple regions and wherein each of the regions has multiple ridges oriented in a different direction than the other regions (see FIG. 3c, ref. #'s 64 and 68). The articulating surface of at least one of the inferior implant or the superior implant is composed of at least one of: cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, or Ti/AlN. The inferior implant and superior implant each range from about 1 mm thick to about 6 mm thick and the inferior implant and superior implant each range from about 3 mm in diameter to about 14 mm in diameter (paragraph [0046]). The cervical facet resurfacing implant comprises a trans-lateral mass fixation mechanism (FIG. 3E, ref. #72) for securing the inferior implant to the inferior articular facet, which comprises a fixation pin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-17 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitz (U.S. Patent No 5,571,191).

Fitz discloses the claimed invention except for the inferior implant and superior implant each range from about 1 mm thick to about 6 mm thick, and the inferior implant and superior implant each range from about 3 mm in diameter to about 14 mm in

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diameter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Fitz with the inferior implant and superior implant each range from about 1 mm thick to about 6 mm thick, and the inferior implant and superior implant each range from about 3 mm in diameter to about 14 mm in diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 16-17 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dooris et al. (U.S. Patent Application Publication 2004/0127989)

Dooris et al. discloses the claimed invention except for the inferior implant and superior implant each range from about 1 mm thick to about 6 mm thick, and the inferior implant and superior implant each range from about 3 mm in diameter to about 14 mm in diameter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Dooris et al. with the inferior implant and superior implant each range from about 1 mm thick to about 6 mm thick, and the inferior implant and superior implant each range from about 3 mm in diameter to about 14 mm in diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 14, 23 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soboleski et al. (U.S. Patent Applicant 2002/0151895) in view of Lee (U.S. Patent Application Publication 2005/0043797).

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Soboleski et al. disclose the claimed invention except for at least one of: a porous coating, a porous onlay material, a biologic coating, a surface treatment, or a material facilitating ingrowth of bone.

Lee discloses using a porous coating to promote bone ingrowth (paragraph [0017]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Soboleski et al. with a porous coating in view of Lee to promote bone ingrowth. Moreover, it is well known in the art to use porous/biological coatings, surface treatments, onlays, and other bone growth promoting materials on the surface of implants.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within


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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER

